AUG 3 2012

3. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K113077

1. Submitter's Identification:
   BIOLAND TECHNOLOGY LTD.
   Room 1122, 11/F., Liven House, 61-63 King Yip Street, Kwun Tong, Kowloon, Hong Kong, China

   Correspondence:
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   Tel: +886-2-6625-8188 #1176
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   Email: teling.hsu@taidoc.com.tw

   Date of preparation: October 14, 2011

2. Device name:
   Proprietary name: BIOLAND G-423 BLOOD GLUCOSE MONITORING SYSTEM, MODEL G-423
   Regulatory information:
   A. Regulation section: 21 CFR § 862.1345, Glucose Test System
   B. Classification: Class II (Glucose Test System)
   C. Product Code: CGA, Glucose Oxidase, Glucose
      NBW, System, Test, Blood Glucose, Over The Counter
   D. Panel: 75, Clinical Chemistry – Glucose Test System

3. Intended Use:

The Bioland G-423 BLOOD GLUCOSE MONITORING SYSTEM is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This system is intended to be used by a single person and should not be shared.

The Bioland G-423 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Bioland G-423 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

The Bioland G-423 Test Strips are for use with the Bioland G-423 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

4. Device Description:

The kit of BIOLAND G-423 BLOOD GLUCOSE MONITORING SYSTEM MODEL G-423 consist of: the meter with blood glucose measurement function and test strips. These products have been designed and tested to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:

A. Predicate device name: Prodigy Blood Glucose System

Predicate K number: k053593

B. Comparison with predicate:

The BIOLAND G-423 BLOOD GLUCOSE MONITORING SYSTEM MODEL G-423 has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- manufactured by the same process.

The differences encompass:

- Software
- Physical appearance
- User interface
- Labeling

6. Test Principle:

   For blood glucose, the detection and measurement is by an electrochemical biosensor technology using glucose oxidase (*A.* Niger).

7. Performance Characteristics:

   Results of the performance tests including system accuracy, user study precision, interference, hematocrit, altitude, meter reliability, storage stability and in-use stability demonstrate that the BIOLAND G-423 BLOOD GLUCOSE MONITORING SYSTEM, MODEL G-423, met the performance requirements for its intended use. Software validation, EMC and safety testing are also performed and the results met the predetermined acceptance criteria. The data demonstrates that the BIOLAND BLOOD GLUCOSE MONITORING SYSTEM MODEL G-423 is substantially equivalent to the predicate device.

8. Conclusion:

   Based on the information provided in this submission, the BIOLAND G-423 BLOOD GLUCOSE MONITORING SYSTEM MODEL G-423 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 3 2012

Taidoc Technology Corporation
c/o Linda Ko
3F, 5F, No. 127, Wugong 2nd Rd
Wugu Township, Wugu Dist.
New Taipei City
China (Taiwan) 24888

Re: k113077
Trade Name: Bioland G-423 Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: July 17, 2012
Received: August 1, 2012

Dear Ms Ko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1.

Indications for Use

510(k) Number (if known): K113077

Device Name: Bioland G-423 Blood Glucose Monitoring System, Model G-423

Indications for Use:
The Bioland G-423 BLOOD GLUCOSE MONITORING SYSTEM is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This system is intended to be used by a single person and should not be shared.

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The Bioland G-423 Test Strips are for use with the Bioland G-423 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

Prescription Use _____	AND/OR	Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113077